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## 12.0 510(K) SUMMARY

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter's name, address, telephone, fax, & contact person

Luxar Corporation

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Phillip Burwell, Product Assurance Manager

2. Date summary prepared:

January 30, 1996

3. Product trade or proprietary name:

Luxar modified LX-20 CO2 Surgical Laser System

4. Product common name:

CO2 Laser

5. Product classification name

21C.F.R. § 878.4810 Lasers in general and plastic surgery and in dermatology

21C.F.R. § 874.4500 Lasers for use in ENT

21C.F.R. § 884.4550 Gynecologic surgical laser

6. Legally marketed predicate device used for equivalency:

Luxar LX-20 CO2 Surgical Laser System (K953074)

7. Description:

The Luxar modified LX-20 surgical laser system produces laser (infrared) energy at a wavelength of 10.6 microns which is directed to soft tissue through a knuckled beam delivery assembly, hollow fiber waveguides, handpieces, and sterile delivery tips.



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8. Statement of intended use:

The intended use of the modified LX-20 is identical to that of the LX-20, namely the vaporization, incision, excision, ablation, or photocoagulation of soft tissue in the listed surgical specialties of:

- Gynecology
- Laparoscopic Surgery including GYN laparoscopy
- Dermatology
- Dental and oral surgery
- Orthopedic
- General Surgery
- Otorhinolaryngology
- Podiatry

No new indications were sought in the premarket notification and no clinical data were presented.

9. Technological characteristics:

The laser output characteristics of the modified LX-20 system and the cleared LX-20 system are identical in average power, increments of power available, and wavelength. The modified LX-20 and the cleared LX-20 share the same RF excited lasing tube, delivery system construction, main chassis, power supply, safety systems, microprocessor controller, and much of the same electronics. The modified LX-20 laser system maintains the same 3 base consoles established pursuant to the predicate K953074 - namely the LX-20i, the LX-20SP, and the LX-20LP. The technological characteristics of the modified LX-20 that are different from the predicate LX-20 are as follows:

The modified unit adds an accessory patterning handpiece and related tip, cabling, and control software and electronics.

Luxar believes that the minor differences in the delivery capabilities of the modified LX-20 and the LX-20 do not raise any new issues of safety and effectiveness.

*Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients or operators due to operator error or in high risk procedures.*